

K062475

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The Laryngeal Mask Company Limited

510(K) SUMMARY

MAY - 9 2007

1. Manufacturer Information

The Laryngeal Mask Company Limited
Le Rocher, Victoria, Mahe, Seychelles

Contact Person: Shirley Sum
Director, Regulatory Affairs and Quality Assurance

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US Agent: Foster Boop
Technical Affairs Director
LMA North America, Inc.
Tel No.: (858) 622 5621
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Date Prepared: 03 August 2006

2. Device Information

2.1 Proposed Device

Trade Name: LMA StoneBreaker™

Common Name: Endoscopic intracorporeal pneumatic lithotriptor

Device Type: Electrohydraulic lithotripter

Classification: Class II

Product Code: FFK

CFR Number: 21 CFR 876.4480

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2.2 Predicate Device

Predicate 1: Swiss LithoClast® (for fragmentation of ureteral and bladder stones) already marketed in the USA under K951531

Predicate 2: Swiss LithoClast® (for fragmentation of ureteral, bladder and kidney stones) already marketed in the USA under K963285

Predicate 3: Swiss LithoClast® Master already marketed in the USA under K974164

3. Device Description

The LMA StoneBreaker™ is a portable, non-electrical, pneumatic contact intracorporeal lithotripter, intended for use to fragment stones in the urinary tract (i.e. kidney, ureter and bladder). Its weight of approximately 500g with a probe, and with no extraneous electrical or pneumatic connections, makes this device highly portable. It is recommended for use with endoscopes equipped with a straight working channel. The device is powered by a detachable cartridge of high pressure carbon dioxide gas, with a maximum pre-adjusted operating pressure of 31 bars. The mechanical shock generated by the device is transferred through the length of the probe to the tip, which is in direct contact with the stone to be fragmented, providing high speed fragmentation of the calculus *in situ*.

Three sizes of probe (1.0mm, 1.6mm and 2.0mm) are available for use with the LMA StoneBreaker™.

A LMA StoneBreaker™ Carbon Dioxide (CO₂) gas cartridge provides the necessary energy for one surgical procedure. Once the cartridge is perforated by the built-in screw system, the compressed gas passes through a pre-adjusted pressure regulator in the device and a mechanical shockwave required for fragmentation of urinary stone is generated when the trigger is depressed.

Expended gas will leave the device through a specially designed exhaust port and the attached exhaust line. The trigger snaps back to its starting

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position when the gas is expended through the exhaust port, and the device is now ready for further use.

The LMA StoneBreaker™, Probes, Exhaust Line and accessories are delivered non-sterile and it must be cleaned, disinfected and sterilized before initial use and before each subsequent use.

4. Intended Use

The LMA StoneBreaker™ is indicated for use via a rigid or semi-rigid endoscope with a straight working channel, for the fragmentation of urinary tract (i.e. kidney, ureter and bladder) stones.

6. Basis for Substantial Equivalence to Predicate Devices

The proposed device is substantially equivalent to predicate devices Swiss LithoClast® and Swiss LithoClast® Master, which were previously cleared for intracorporeal fragmentation of ureteral and bladder stones under K951531, for kidney stones under K963285 and for kidney, ureteral and bladder stones under K974164. The main differences between the LMA StoneBreaker™ and predicate devices are:

- **Portability** - The proposed device is hand-held portable lithotripter. Predicate devices are non-portable lithotripter.
- **Energy Source** - The proposed device is powered by detachable Carbon dioxide gas cartridge. Predicate devices are powered by connection to compressed air.

6. Performance Characteristics

Performance and clinical data are shown in Section 2. The operational, technological and clinical data demonstrate that the LMA StoneBreaker™ is substantially equivalent in safety and effectiveness to that of the predicated devices cited above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

The Laryngeal Mask Company Ltd.
c/o Mr. Foster Boop
Technical Affairs Director
LMA™ North America, Inc.
4660 La Jolla Village Drive, Suite 900
SAN DIEGO CA 92122

MAY - 9 2007

Re: K062475
Trade/Device Name: LMA StoneBreaker™
Regulation Number: 21 CFR §876.4480
Regulation Name: Electrohydraulic lithotripter
Regulatory Class: II
Product Code: FFK
Dated: March 13, 2007
Received: March 14, 2007

Dear Mr. Boop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
<http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Applicant: The Laryngeal Mask Company Limited

510(k) Number (if known): K 0 6 2 4 7 5

Device Name: LMA StoneBreaker™

Indications for Use:

The LMA StoneBreaker™ is indicated for use via a rigid or semi-rigid endoscope with a straight working channel, for the fragmentation of urinary tract (i.e. kidney, ureter and bladder) stones.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancye Brodson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K 0 6 2 4 7 5